IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

TEVA PHARMACEUTICALS USA, INC., Plaintiff, v. ASTRAZENECA PHARMACEUTICALS LP, and AMYLIN PHARMACEUTICALS, LLC, Defendants.	)	C.A. No. _____

COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiff Teva Pharmaceuticals USA, Inc. ("Teva USA") brings this action for a declaratory judgment of patent non-infringement against Defendants AstraZeneca Pharmaceuticals LP ("AstraZeneca LP") and Amylin Pharmaceuticals, LLC ("Amylin") (collectively, "Defendants").

STATEMENT OF THE CASE

1. This is a declaratory judgment action by Teva USA against Defendants seeking a judgment declaring that Teva USA has not infringed and will not infringe any valid and enforceable claim of United States Patent Nos. 7,297,761 ("the '761 patent") and 7,741,269 ("the '269 patent").

2. Defendants listed the '761 and '269 patents, together with six other patents, in the U.S. Food and Drug Administration's ("FDA") *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") with respect to Byetta® as patents that could reasonably be asserted against anyone selling or seeking to sell a generic version of Byetta®.

3. Teva USA has filed Abbreviated New Drug Application No. 205984("Teva USA's ANDA") with the FDA, seeking approval to engage in the commercial manufacture, use, or sale of Exenatide Injection 300mcg/1.2 mL and 600 mcg/2.4 mL (250 mcg/mL) ("Teva USA's ANDA Products"), which would be generic versions of Byetta®. In Teva USA's ANDA, Teva USA filed a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certification") with respect to seven of the patents listed in the Orange Book for Byetta®, including the '761 and '269 patents. Teva USA then provided Defendants with notice that Teva USA had submitted Teva USA's ANDA with a Paragraph IV certification as to those seven patents (hereinafter, "Teva USA's Notice Letter").

4. Within 45 days of receiving Teva USA's Notice Letter (hereinafter, "the 45-day period"), Defendants and AstraZeneca AB filed a Complaint for Patent Infringement in this Court against Teva USA for infringement of five of those patents ("Complaint for Patent Infringement"), but not the '761 and '269 patents. While the 45-day period has since expired, Defendants have (1) failed to initiate litigation with respect to the '761 and '269 patents and (2) refused Teva USA's request that they give Teva USA a covenant not to sue with respect to the '761 and '269 patents.

5. For these reasons, Teva USA has a reasonable apprehension that Defendants will sue it for infringement of the '761 and '269 patents at a time of their choice and for the purpose of impairing Teva USA's ability to sell its ANDA Products in the United States. Teva USA thus seeks a declaratory judgment that it does not infringe and is not liable for infringement of the '761 and '269 patents.

THE PARTIES

6. Plaintiff Teva USA is a Delaware corporation with a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.

7. Defendant AstraZeneca LP averred in the Complaint for Patent Infringement that it is a limited partnership organized under the laws of Delaware, and with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19850.

8. Defendant Amylin has averred in the Complaint for Patent Infringement that it is organized under the laws of the State of Delaware, with its principal place of business at 9625 Towne Centre Drive, San Diego, California 92121. Upon information and belief, Amylin permanently maintains an agent in Delaware who is authorized by Amylin to receive service of process in this jurisdiction.

JURISDICTION AND VENUE

9. This is an action for a declaration that Teva USA has not infringed and will not infringe the '761 and '269 patents. Subject matter jurisdiction of this Court exists under the Federal Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and 28 U.S.C. §§ 1331 and 1338(a). This Court also has subject matter jurisdiction over this action under 35 U.S.C. § 271(e)(5) and 21 U.S.C. § 355(j)(5)(C) because the 45-day period has expired, Defendants have failed to bring a civil action against Teva USA for infringement of the '761 and '269 patents before expiry of the 45-day period, and Teva USA has provided Defendants with an offer of confidential access ("OCA") pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III), together with materials pursuant to the OCA, which OCA was accepted by Defendants.

10. Defendants have subjected themselves to the Court's personal jurisdiction by filing the Complaint for Patent Infringement in this Court, and thereby consenting to its jurisdiction. This Court also has personal jurisdiction over Defendants for at least the reasons that both Defendants have averred that they are incorporated in the State of Delaware and that AstraZeneca LP has a principal place of business in Delaware.

11. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE ORANGE BOOK LISTING FOR BYETTA®

12. Defendants listed the '761 and '269 patents, as well as six other patents, in the Orange Book with respect to Byetta®.

13. The '761 patent, titled "Pharmaceutical compositions containing exendins," issued on or about November 20, 2007. The assignment database of the United States Patent and Trademark Office ("PTO") indicates that Defendants jointly own the '761 patent. A true and correct copy of the '761 patent is attached hereto as Exhibit A.

14. The '269 patent, titled "Exendins and exendin agonists for weight reduction and obesity," issued on or about June 22, 2010. The PTO's assignment database indicates that Defendants jointly own the '269 patent. A true and correct copy of the '269 patent is attached hereto as Exhibit B.

15. The six other patents listed in the Orange Book with respect to Byetta® are U.S. Patent Nos. 6,858,576 ("the '576 patent"), 6,872,700 ("the '700 patent"), 6,956,026 ("the '026 patent"), 6,902,744 ("the '744 patent"), 7,521,423 ("the '423 patent") and 5,424,286.

TEVA USA'S ANDA

16. Teva USA's ANDA included a Paragraph IV certification, seeking approval to engage in the commercial manufacture, use or sale of Teva USA's ANDA Products prior to the expiration of the '761 and '269 patents, as well as prior to the expiration of the '576, '700, '026, '744 and '423 patents.

17. On October 30, 2014, Teva USA, in accordance with 35 U.S.C. § 355(j)(2)(B), sent to Defendants and others Teva USA's Notice Letter, which provided "detailed statements of the factual and legal bases for Teva USA's opinion the '576, '700, '744, '026, '761, '423 and

'269 patents are not valid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of Teva USA's product." Upon information and belief, Defendants received Teva USA's Notice Letter on October 31, 2014.

18. Teva USA also provided Defendants with an OCA pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III). On or before December 3, 2014, outside counsel for Defendants signed Teva USA's OCA and thereby accepted Teva USA's OCA on behalf of Defendants. On December 5, 2014, outside counsel for Teva USA produced portions of Teva USA's ANDA to outside counsel for Defendants pursuant to the OCA. Upon information and belief, later that same day, outside counsel for Defendants received the portions of Teva USA's ANDA that Teva USA's outside counsel had produced.

DEFENDANTS' FAILURE TO INITIATE LITIGATION REGARDING THE '761 AND '269 PATENTS AND REFUSAL TO PROVIDE A COVENANT NOT TO SUE

19. On December 12, 2014, which is within 45 days of Defendants having received Teva USA's Notice Letter, Defendants and AstraZeneca AB filed the Complaint for Patent Infringement, which alleged infringement of the '576, '700, '744, '026 and '423 patents, but did not allege infringement of the '761 and '269 patents.

20. Defendants did not file, nor has anyone else filed, any suit asserting infringement of the '761 and '269 patents against Teva USA within the 45-day period following Defendants' receipt of Teva USA's Notice Letter.

21. Teva USA, through its outside counsel, has requested from Defendants that they provide Teva USA with a covenant not to sue it with respect to the '761 and '269 patents. As of the filing date of this Complaint for Declaratory Judgment, however, and notwithstanding Teva USA's requests for a covenant not to sue, Defendants have not provided Teva USA with such a covenant.

THE PRESENCE OF A CASE OR CONTROVERSY

22. Under 35 U.S.C. § 271(e)(2)(A), Teva USA's Paragraph IV certification constitutes an "artificial" act of infringement with respect to each such patent that was subject to that certification. Thus, Teva USA committed an "artificial" act of infringement with respect to the '761 and '269 patents. Teva USA, however, has not infringed, nor is it liable for infringement of, either of these two patents.

23. Because Defendants filed their Complaint for Patent Infringement against Teva USA alleging that Teva USA has infringed the '576, '700, '744, '026 and '423 patents, Defendants have demonstrated an intent to enforce their patents concerning Byetta®.

24. Defendants never disavowed, in their Complaint for Patent Infringement or elsewhere, an intent to assert that Teva USA infringes the '761 and '269 patents. Teva USA has requested from Defendants that they provide Teva USA with a covenant not to sue, but Defendants have not provided one and have indeed refused Teva USA's request.

25. Teva USA has made, and will continue to make, substantial preparation in the United States to obtain FDA approval of ANDA No. 205984.

26. For these reasons, Teva USA has a reasonable apprehension that Defendants will sue Teva USA for infringement of the '761 and '269 patents at a time of their choosing and for the purpose of impairing Teva USA's ability to sell its ANDA Products in the United States.

27. An actual justiciable controversy therefore exists between the parties as to the non-infringement of the '761 and '269 patents.

28. To avoid legal uncertainty and to protect its substantial investment and anticipated future investment in Teva USA's ANDA Product, Teva USA brings these claims for a declaration of rights with respect to the '761 and '269 patents.

29. Resolving this controversy with a declaration of rights would serve the public policy interest of the Hatch-Waxman Act in encouraging generic competition by allowing early resolution of patent disputes that could impede public access to generic drug products.

COUNT I
Declaratory Judgment of Non-Infringement,
United States Patent No. 7,297,761

30. Teva USA incorporates by reference and re-alleges the allegations in paragraphs 1 through 29 as if fully set forth herein.

31. An actual controversy exists between Defendants and Teva USA concerning the non-infringement of the '761 patent, which requires a declaration of rights by this Court.

32. Teva USA has not infringed and is not liable for infringement of the '761 patent.

33. Teva USA is entitled to a declaratory judgment that Teva USA has not infringed and is not liable for infringement of any valid and enforceable claim of the '761 patent, and that the commercial manufacture, use, offer for sale, sale or importation of Teva USA's ANDA Products would not infringe any valid and enforceable claim of the '761 patent, either literally or under the doctrine of equivalents.

COUNT II
Declaratory Judgment of Non-Infringement,
United States Patent No. 7,741,269

34. Teva USA incorporates by reference and re-alleges the allegations in paragraphs 1 through 33 as if fully set forth herein.

35. An actual controversy exists between Defendants and Teva USA concerning the non-infringement of the '269 patent, which requires a declaration of rights by this Court.

36. Teva USA has not infringed and is not liable for infringement of the '269 patent.

37. Teva USA is entitled to a declaratory judgment that Teva USA has not infringed and is not liable for infringement of any valid and enforceable claim of the '269 patent, and that the commercial manufacture, use, offer for sale, sale or importation of Teva USA's ANDA Products would not infringe any valid and enforceable claim of the '269 patent, either literally or under the doctrine of equivalents.

PRAYER FOR RELIEF

WHEREFORE, Teva USA respectfully requests that this Court grant the following relief against Defendants:

A. A judgment declaring that Teva USA has not infringed and is not liable for infringement of any valid and enforceable claim of the '761 and '269 patents, and that the commercial manufacture, use, offer for sale, sale or importation of Teva USA's ANDA Products would not infringe any valid and enforceable claim of the '761 and '269 patents, either literally or under the doctrine of equivalents;

B. An award to Teva USA of its costs and expenses in this action

C. A determination that this is an exceptional case and an award to Teva USA of reasonable attorney fees and costs pursuant to 35 U.S.C. § 285; and

D. Such other and further relief as this Court may deem just.

Respectfully submitted,

/s/ John W. Shaw

John W. Shaw (No. 3362)
Karen E. Keller (No. 4489)
SHAW KELLER LLP
300 Delaware Ave., Suite 1120
Wilmington, DE 19801
(302) 298-0700
jshaw@shawkeller.com
kkeller@shawkeller.com

Attorneys for Defendant
Teva Pharmaceuticals USA, Inc.

OF COUNSEL:
Ira J. Levy
Frederick H. Rein
Joshua A. Whitehill
GOODWIN PROCTER LLP
The New York Times Building
620 Eighth Avenue
New York, NY 10018
(212) 813-8800

Elaine H. Blais
Srikanth K. Reddy
Molly R. Grammel
GOODWIN PROCTER LLP
Exchange Place
53 State Street
Boston, MA 02109
(617) 570-1000

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